K011920

JUL - 2 2001

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
For Emit® 2000 Digoxin Assay

1. **Manufacturer and Contact Information:**

Manufacturer: Syva Company – Dade Behring Inc.
20400 Mariani Ave.
Cupertino, CA 95014

Contact Information: Susan L. Collins
Regulatory Affairs
Syva Company – Dade Behring, Inc.
20400 Mariani Avenue
Cupertino, CA 95014
Tel: 408 – 366-3908
Fax: 408 – 366-3725

2. **Date Summary Prepared:**
June 19, 2001

3. **Device Trade Name:**
Emit® 2000 Digoxin Assay

4. **Common Name:**
Enzyme Immunoassay, Digoxin

5. **Device Classification Name:**
The Clinical Chemistry and Clinical Toxicology Devices Panel have classified "Digoxin test system" as Class II, 21 CFR Part 862.3320, 91 KXT.

6. **Intended Use:**
The Emit® 2000 Digoxin Assay is a homogeneous enzyme immunoassay intended for use in the quantitative analysis of digoxin in human serum or plasma. These reagents are packaged specifically for use on a variety of OLYMPUS® analyzers.

7. **Device Description:**
The modified assay is similar to the predicate device with minor differences in the packaging of the product. The modified assay has a smaller fill volume of the reagents into different shaped (wedge) reagent bottles. Both the predicate and modified device reagent bottles are made of the same material (HDPE). The modified reagent bottles incorporate a barcode label with assay specific information and are compatible with the OLYMPUS® AU400/600™, AU800/1000™ and AU2700™ Series Analyzers.

8. **Substantial Equivalence**

The modified device has the same operating principles, design, manufacturing materials, method of manufacture, assay performance characteristics and intended use as the predicate device. In conclusion the modified Emit® 2000 Digoxin Assay is substantially equivalent to the predicate Emit® 2000 Digoxin Assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ms. Susan L. Collins
Regulatory Affairs
Syva Company – Dade Behring Inc.
20400 Mariani Avenue
Cupertino, CA 95014

Re: 510(k) Number: K011920
Trade/Device Name: Emit® 2000 Digoxin Assay
Regulation Number: 862.3320
Regulatory Class: II
Product Code: KXT
Dated: June 19, 2001
Received: June 20, 2001

Dear Ms. Collins:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K011920 **Device Name:** Emit® 2000 Digoxin Assay

Indications for Use:

The Emit® 2000 Digoxin Assay is a homogeneous enzyme immunoassay intended for use in the quantitative analysis of digoxin in human serum or plasma. Measurements obtained from this device are used in the diagnosis and treatment of digoxin overdose or in monitoring levels of digoxin to ensure appropriate therapy. These reagents are packaged specifically for use on a variety of OLYMPUS® analyzers.

Fred Lacy
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011920

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✔ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)